K070500
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510(K) Summary

JUL 16 2007

Submitter:

N. I. Medical, Ltd.
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Israel

Contact Person:

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Date Prepared: February 19, 2007

Device Trade Name: NICaS 2004 Slim Bioimpedance Cardiac Analyzing Measuring System

Common/Usual name: Bioimpedance Cardiac Analyzing measuring System

Classification name: Impedance Plethysmograph

Predicate Devices: NICaS 2001 Noninvasive Cardio-Respiratory System (510(k) number 942227)

Device Description:

The NICaS (non-invasive cardiac system) is a CD-ROM shaped device which replaces the actual CD-Rom of a laptop computer. It is used for noninvasive cardiac diagnostic purposes.

The NICaS (non-invasive cardiac system) *SLIM 2004* is an impedance device which is unique in its use of a laptop computer *as* part *of a* technology for non-invasively measuring the cardiac output and its derivatives. The NICaS is also unique in that it is the only method of impedance cardiography (ICG) which utilizes only two pairs of impedance electrodes, placed on two limbs, preferably one pair on the wrist, and the other on the contra-lateral ankle. This type of electrical surveillance is called regional ICG, or RIC.

The NICaS is a tetrapolar apparatus which operates by an alternating current of 1.4 mA and 32 kHZ.

The principle of this technology is based on the fact that the electrical conductance of the blood is higher than that of the surrounding tissue structures. Consequently, with each arterial systolic expansion (pulsation), an increase in the electrical conductance (or reduction in the electrical resistance) of the body is measured. This systolic resistance (impedance) change is termed ❑R, and the baseline body resistance is R (0).

The analog resistance signals are received by the device, where they are amplified and filtered. These signals are then transmitted to a microprocessor, where they are digitized and analyzed via mathematical algorithms.

Indications for Use:

The NICaS 2004 Slim is intended for use in monitoring hemodynamic parameters (including stroke volume, stroke index, heart rate, cardiac index, cardiac output, and total peripheral resistance), in males and females needing cardiac output assessment, including patients with cardiac disorders, patients undergoing cardiac catheterization, cardiac surgery patients and patients in intensive and cardiac care units and rehabilitation.

Statement of Technical Comparison;

The NICaS 2004 Slim bioimpedance cardiac analyzing measuring system is substantially equivalent to the NICaS 2001 non-invasive cardio-respitory system which was cleared under 510(k) number K942227. Both of these devices were developed by and are manufactured for N.1. Medical, Ltd., Israel. Both are also used for used for noninvasive cardiac diagnostic purposes.

The principle of the technology used by both devices is based on the fact that the electrical conductance of the blood is higher than that of the surrounding tissue structures. Consequently, with each arterial systolic expansion (pulsation), an increase in the electrical conductance (or reduction in the electrical resistance) of the body is measured. This systolic resistance (impedance) change is termed ❑R, and the baseline body resistance is R (0).

The analog resistance signals are received by the devices, where they are amplified and filtered. These signals are then transmitted to a microprocessor, where they are digitized and analyzed via mathematical algorithms. The data are portrayed on the computers screen

The following table lists the differences between the devices:

Attribute	Predicate Device NICaS 2001	NICaS 2004 Slim
1. Computer Connection	Outside computer-connected via cable	Fits into the computer CD-ROM area
2. Leads	Bipolar (2 leads) with clips	Tetrapolar (4 leads) with snaps
3. Body connection	Straps	ECG snap electrodes
4. Mathematical data analysis	Algorithm	Improved algorithm providing greater mathematical precision

NON-clinical Testing:

The NICaS 2004 Slim has been tested and found to comply with the requirements of IEC 60601-1-1.

The NICaS 2001 and the NICaS 2004 were attached to a simulator and fifty readings were taken. In all cases, the the NICaS 2004 exhibited significantly improved readings when compared to the NICaS 2001.

Clinical Testing:

The NICaS 2004 Slim was used on one hundred sixty three patients and the readings were compared to thermodilution on the same patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2007

NI Medical, Inc.
c/o Mr. James Collie
Consultant
J. R. Collie Associates, Inc.
414 Maryjoe Way
Warrington, PA 18976

Re: K070500
Trade Name: Bioimpedance Cardiac Analyzing Measuring System
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB
Dated: June 11, 2007
Received: June 13, 2007

Dear Mr. Collie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070500

Device Name: NICaS 2004 SLIM

Indications for Use:

The NICaS 2004 Slim is intended for use in monitoring hemodynamic parameters (including stroke volume, stroke index, heart rate, cardiac index, cardiac output, and total peripheral resistance), in males and females needing cardiac output assessment, including patients with cardiac disorders, patients undergoing cardiac catheterization, cardiac surgery patients and patients in intensive and cardiac care units and rehabilitation.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070500